

EXAMINER'S AMENDMENT AND REASONS FOR ALLOWANCE

1. The response, remarks and amendments filed 24 February 2009 in response to the Notice of Non-Compliant Amendment mailed 17 February is acknowledged and entered.
2. Additionally, the response, remarks and amendments filed 28 October 2008 in response to the Office Action mailed 28 July 2008 is acknowledged and entered.

Informal Matters

3. The Office Action that follows addresses remarks and amendments presented in each of the responses and amendments filed 28 October 2008 and 24 February 2009 respectively.

Withdrawal of Rejections based on Applicant's Amendments

4. In consideration of amendments and remarks filed 28 October 2008 and on 24 February 2009, following objections and rejections in Office Action mailed 28 July 2008 are hereby withdrawn:
 - Anticipatory rejection of Claim 1 under 35 U.S.C. §102(b) as anticipated by Schankereli (U.S. Patent 5, 782,914 A); and
 - Obviousness rejection of Claims 1, 32-35, 52 and 64 under 35 U.S.C. § 103 (a) as obvious over the combined teachings from Schankereli (U.S. Patent 5, 782,914 A) in view of Bertiger (US Patent 4,538,757).

Claims Status

5. Claims 2-31, 36-51, 53-63 and 65-88 remain cancelled.
6. Claims 1, 32-35, 52 and 64 are currently pending.
7. Claims 1, 32-35, 52 and 64 are currently pending and are examined on merits.

Information Disclosure Statement

8. Information Disclosure Statement (i.e., IDS) filed 24 February 2009 is acknowledged, has been made of record, considered and duly signed copy of USPTO FORM SB 08A is enclosed with the instant Office Action.

Examiner's Amendment

9. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on 06-08 and 11 May 2009 with Ms. Alicia Mills, Applicants' Representative.

In the Claims

Please amend the Claims as follows:

Listing of Claims:

1. (Currently Amended) A method effective to protect one or more properties of a biological material or device containing said biological material during the process of sterilization which comprises:
 - a) packaging the biological material;
 - b) providing a protective atmosphere within the package, wherein providing a protective atmosphere within the ~~package packaging~~ of the packaged biological material is carried out by: ~~at least partially~~ removing an original atmosphere under vacuum [[,]] and replacing the original atmosphere, wherein removing and replacing is done by evacuating and backfilling the original atmosphere in the package, flushing the original atmosphere in the package, or substituting the original atmosphere in the package, and wherein replacing the original atmosphere is done with a protective atmosphere comprising a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere;
 - c) sterilizing the packaged biological material or device containing said biological material in the presence of said protective atmosphere to reduce and/or inactivate an adventitious agent or adventitious agents.

2-31 (Canceled)

32. (Currently Amended) The method of claim 1, wherein the inert atmosphere comprises ~~at least one inert gas selected from the group consisting of nitrogen and argon.~~

33. (Currently Amended) The method of Claim 1, wherein the reducing atmosphere comprises at least one reducing gas selected from the group consisting of hydrogen ~~[[,]]~~ and hydrogen sulfide ~~and carbon monoxide.~~

34. (Currently Amended) The method of Claim 1, wherein the mixture of inert atmosphere and reducing atmosphere contains from about 5 to about 30% ~~0.5 to about 99%~~ by volume reducing atmosphere gas.

35. (Currently Amended) The method of Claim 1, wherein the original atmosphere is ~~at least partially~~ removed under a vacuum of from about 1 to about 200 torr.

36-51 (Canceled)

52. (Previously Presented) The method of Claim 1, wherein the biological material is bone.

53-63 (Canceled)

64. (Currently Amended) The method of Claim 1, wherein the biological material is selected from the group consisting of food, tissue and therapeutically useful substance ~~and therapeutically useful device.~~

65-88 (Canceled)

89. (new) the method of claim 1, wherein the inert atmosphere comprises argon.

90. (New) The method of Claim 1, wherein the inert atmosphere comprises helium.

91, (New) The method of Claim 1, wherein the inert atmosphere comprises neon.

92, (New) The method of Claim 1, wherein the inert atmosphere comprises krypton.

93. (New) The method of Claim 1, wherein the inert atmosphere comprises xenon.

94. (New) The method of Claim 1, wherein the inert atmosphere comprises carbon dioxide.

95. (New) The method of claim 1, wherein removing and replacing is done by removing an original atmosphere under vacuum and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere.

96. (New) The method of claim 1, wherein removing and replacing is done by evacuating an original atmosphere under vacuum and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere.

97. (New) The method of claim 1, wherein removing and replacing is done by substituting an original atmosphere under vacuum and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere.

98. (New) The method of claim 1, wherein removing and replacing is done by flushing an original atmosphere under vacuum and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and reducing atmosphere, wherein the mixture of an inert atmosphere and a reducing atmosphere contains about 0.5 to about 99% by volume reducing atmosphere.

Examiner's Reasons for Allowance

10. The following is Examiner's statement of reasons for allowance:

The closest art references are:

➤ U.S. Patent 5, 782,914 A, issued 21 July 1998 to Schankereli.

Schankereli teaches a method for radiation sterilization of a vacuum-dried tissue contained in a pouch and further teaches that evacuation and/ or replacement of the atmosphere within the tissue package using argon or nitrogen limits free radical formation (i.e., oxidation) of the tissue during radiation sterilization, thus inhibiting chemical and physical damage to the tissue (Column 3, Lines 57 to Column 4, Line 22).

Schankererli, however, does not teach total or at least even partial evacuation, flushing, replacement, or removal of the atmosphere within said pouch and replacing the original atmosphere within said pouch with a reducing atmosphere or a mixture of a reducing atmosphere and an inert atmosphere.

- US Patent 4,538,757 issued 03 September 1985 to Bertiger.

Bertiger discloses a method to prevent oxidation of a material in the presence of an atmosphere that comprises 85% nitrogen and 15% hydrogen.

Bertiger, however, does not teach a method wherein said atmosphere comprises 85% nitrogen and 15% hydrogen replaces either totally or partially the atmosphere in a pouch, wherein the original atmosphere in said pouch has been either partially or totally evacuated, flushed, removed or substituted with said atmosphere comprising 85% nitrogen and 15% hydrogen (i.e., mixture of same reducing and inert gas as has been instantly claimed). Furthermore, while Bertiger teaches prevention of oxidation, said oxidation prevention is not during sterilization of a biological material or a device comprising said biological material in a mixture of an inert and a reducing atmosphere.

Thus, none of the references cited *supra*, either separately or in combination; teach each and every feature of the claimed invention. Consequently, the instantly claimed invention in Claims 1, 32-35, 52, 64 and 89-98 is neither anticipated, nor is obvious over the combined teachings of any, or all above-cited art references.

11. Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

12. Claims 1, 32-35, 52, 64 and 89-98 are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657

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09 May 2009

/JON P WEBER/
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